



OBRR

Office of Biorepositories
and Biospecimen Research

Biospecimen Data Is Critical to Realizing Personalized Medicine

Carolyn C. Compton, M.D., Ph.D.

Director, Office of Biorepositories and Biospecimen Research

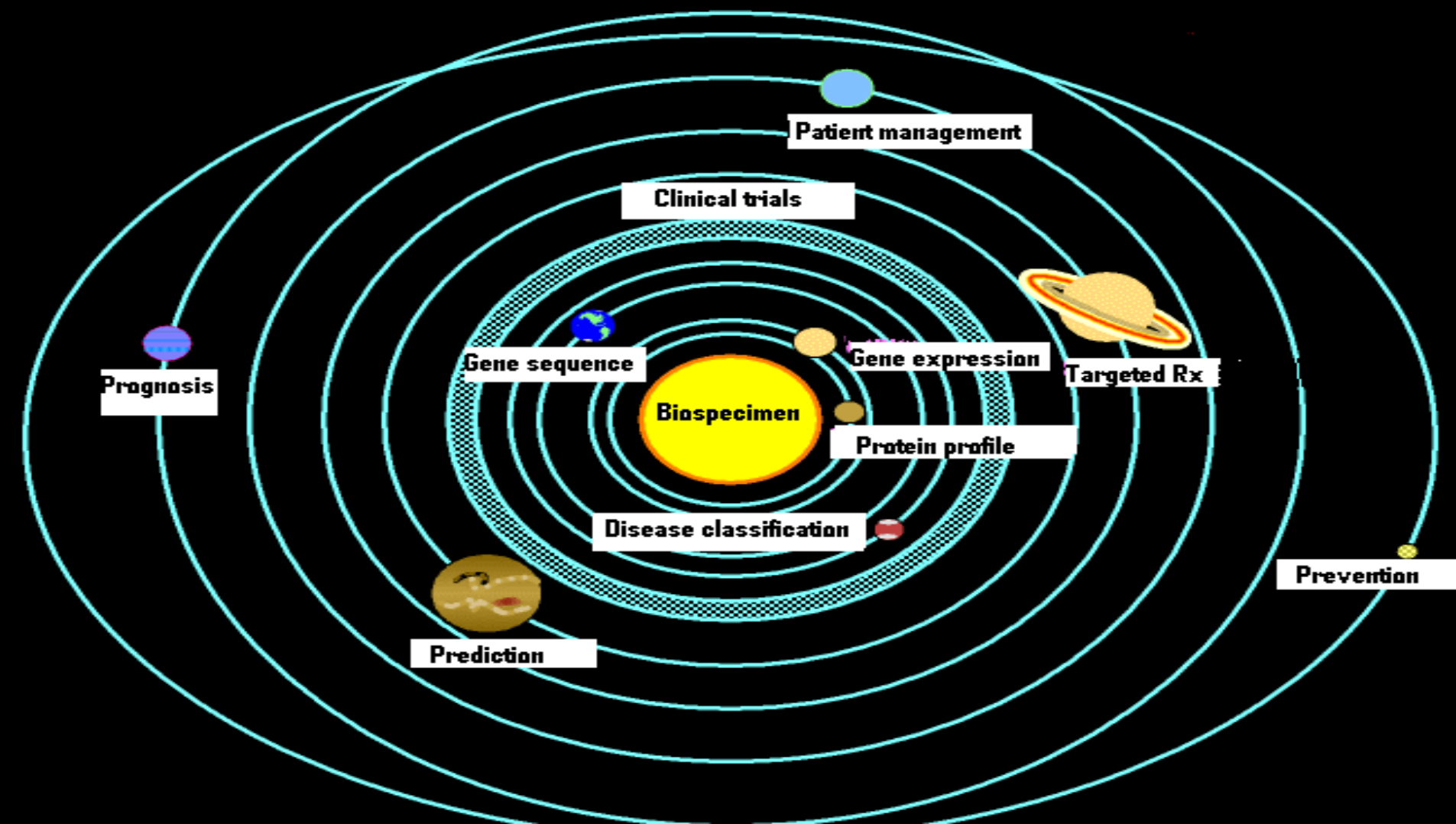
Biomedical Informatics Without Borders
June 21, 2010

NATIONAL
CANCER
INSTITUTE



The Personalized Medicine Universe

OBBR Office of Biorepositories
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The Demand for High Quality Human Specimens Across the NCI

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Identification of targets for drug development, treatment and prevention

Identify biologic variations that determine drug efficacy and drug toxicity

Defining markers for susceptibility, screening and reoccurrence

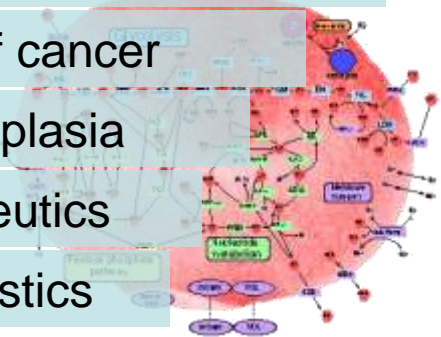
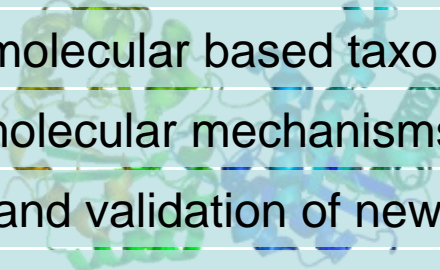
Development of molecular based taxonomy of cancer

Elucidation of molecular mechanisms of neoplasia

Development and validation of new therapeutics

Development and validation of new diagnostics

**All Depend
On High-Quality, Annotated
Human Biospecimens**





OBBR's Strategies: Solutions Built on Informatics

OBBR Office of Biorepositories
and Biospecimen Research

Stepwise Approach to Solutions:

- Standards
 - The NCI's *Best Practices for Biospecimen Resources*
- Science
 - The Biospecimen Research Network
- Specimens and Service
 - The Cancer Human Biobank



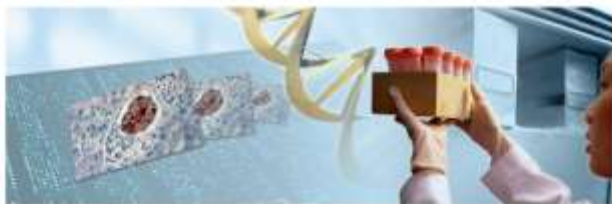
What Is a Biospecimen Resource?

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NCI defines a biospecimen resource as a collection of human specimens and associated data for research purposes, the physical entity where the collection is stored, and all relevant processes and policies.

NCI's Best Practices for Biospecimen Resources: <http://biospecimens.cancer.gov>

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National Cancer Institute Best Practices for Biospecimen Resources

June 2007

Prepared by:
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

- State-of-the-science baseline for operating standards on which to build as the state of the science evolves
- Unifying policies and procedures for biospecimen resources supported by the NCI or used by NCI-supported investigators
- Web version 2009 capabilities:
 - Hyperlinks to outside resources and references
 - Internal links between various sections
 - Search functionality
- First step to improve the quality of human biospecimens used in cancer research
- Update in 2009-10; release to Federal Register this month



The NCI Best Practices Overview

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NCI Best Practices include recommendations for:

- Technical, operational and safety best practices
- Quality assurance and quality control programs
- Implementation of enabling informatics systems
- Addressing ethical, legal, and policy issues
- Establishing reporting mechanisms
- Providing administration and management structure
- Definitions of key terms



OBBR's Strategic Plan

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and Biospecimen Research

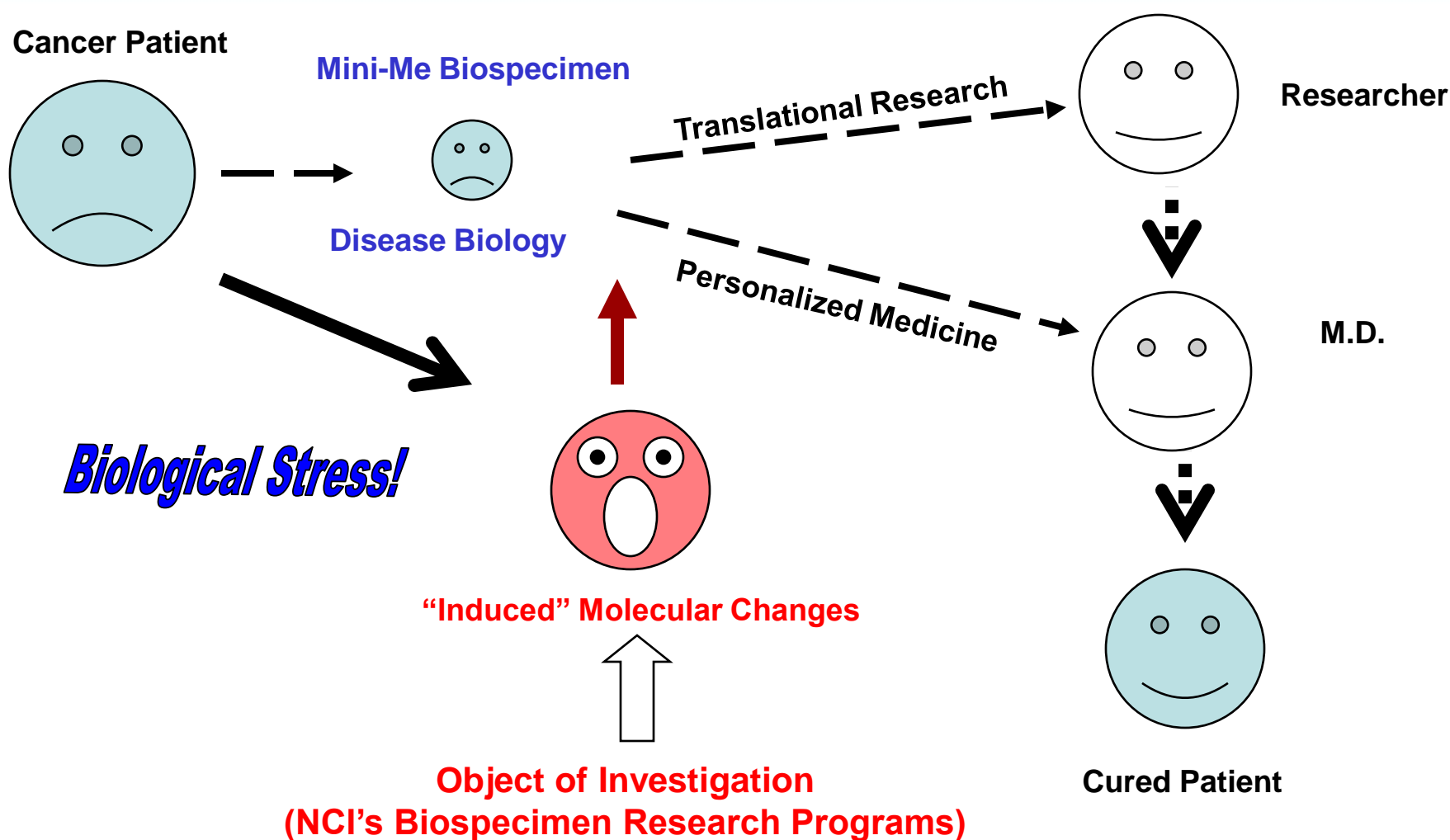
Stepwise Approach to Solutions:

- Standards
 - The NCI's *Best Practices for Biospecimen Resources*
- Science and Technology
 - The Biospecimen Research Network
 - The Innovative Molecular Analysis Technologies
- Specimens and Service
 - The Cancer Human Biobank



Understanding the Biology of Biospecimens: The Goal of Biospecimen Science

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Pre-analytical Variables Can Affect Molecular Composition and Integrity

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Variables (examples):

- Antibiotics
- Other drugs
- Type of anesthesia
- Duration of anesthesia
- Arterial clamp time

Time 0

Variables (examples):

- Time at room temperature
- Temperature of room
- Type of fixative
- Time in fixative
- Rate of freezing
- Size of aliquots



Patient

Medical/
Surgical
Procedures

Acquisition

Handling/
Processing

Storage

Distribution

Scientific
Analysis

Restocking
Unused
Sample

Pre-acquisition

Post-acquisition

How Can Changes in Molecular Integrity of Biospecimens Affect Molecular Readout?

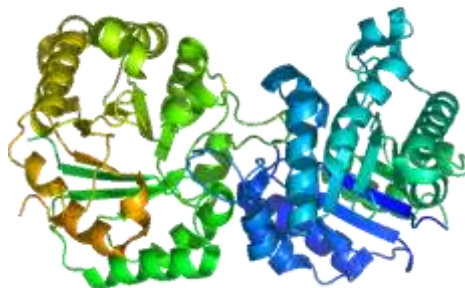
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Genomics



- Changes in specific transcript levels based on ischemic time, for example, not disease
- Change in RNA levels with frozen storage time or freeze-thaw cycles

Proteomics



- Lack of reproducibility of protein biomarkers in discovery research
- Inconsistent IHC results in research and clinical labs

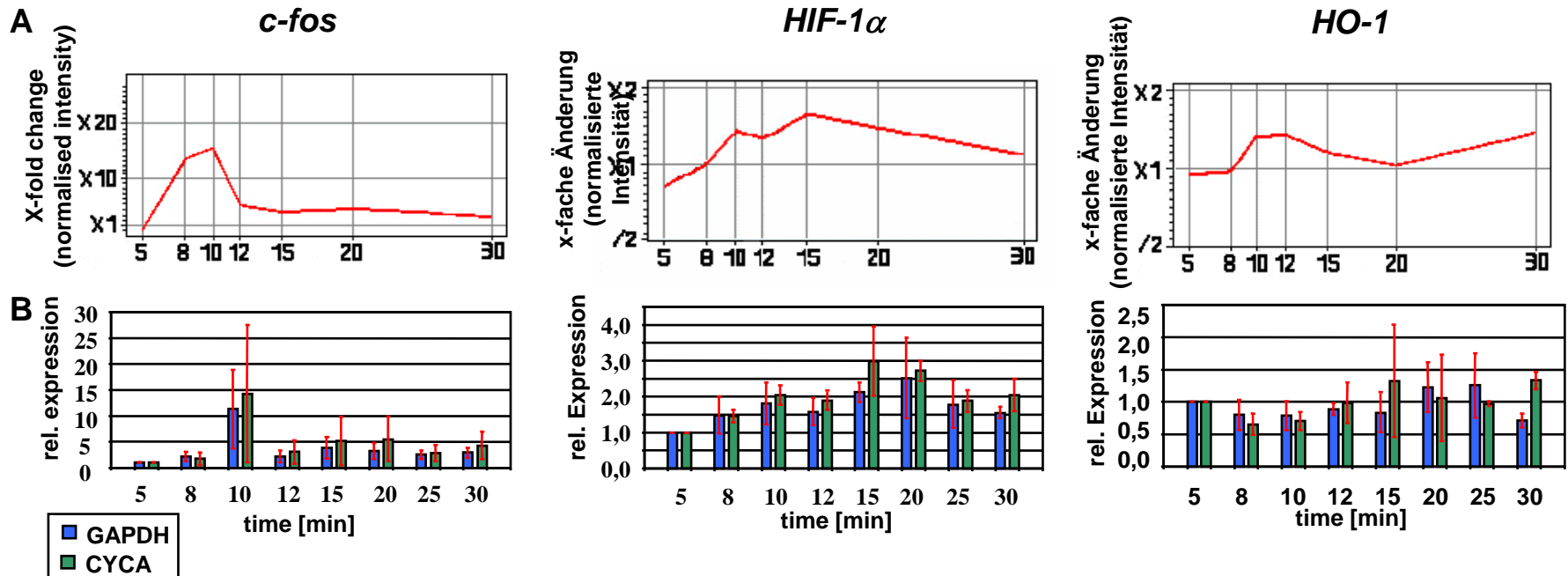
Metabolomics



Inconsistencies in small molecule readouts, yielding results that point to the wrong pathway

Postsurgical Ischemia and Gene Expression

Ischemia regulated genes *c-fos*, HIF- α and HO-1

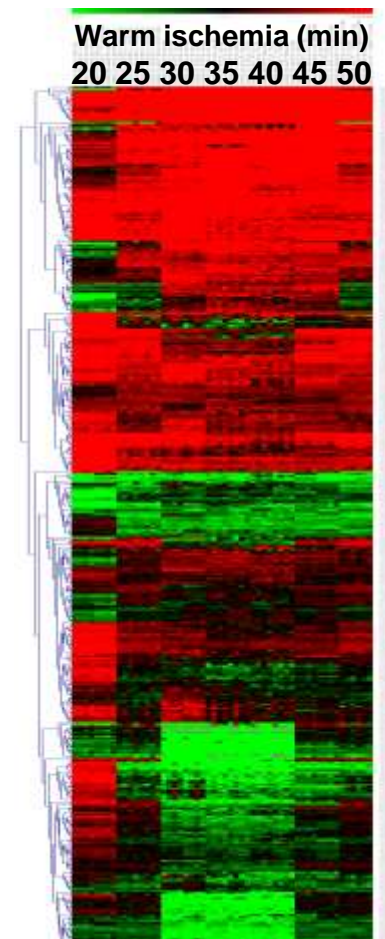
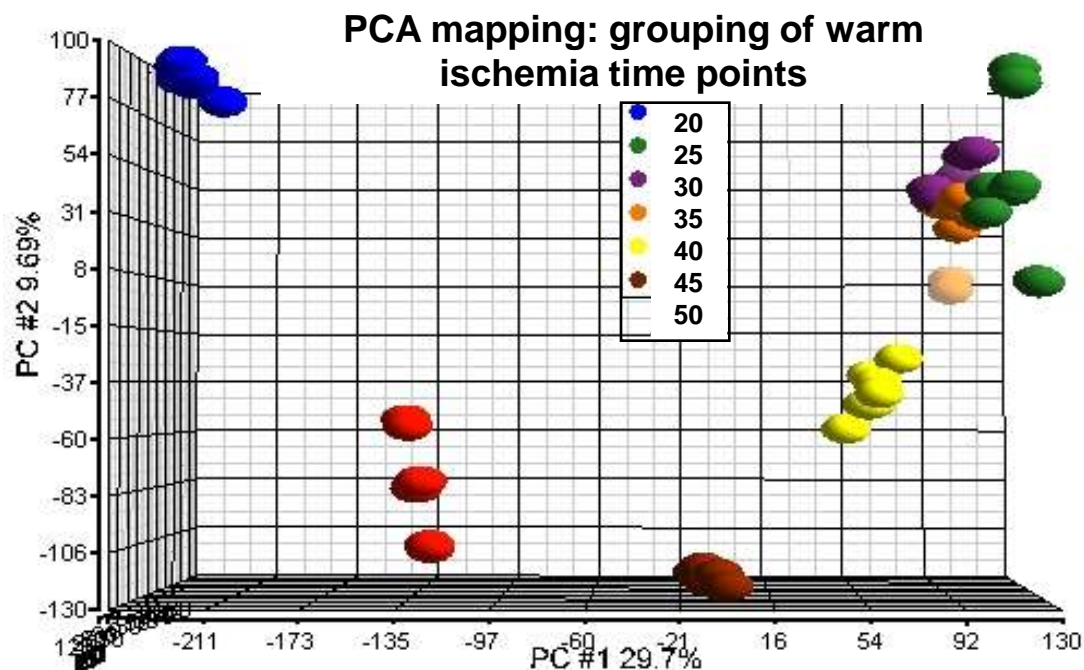


Tissue ischemia and gene expression profiling (Comparison Affymetrix data and real-time RT-PCR)



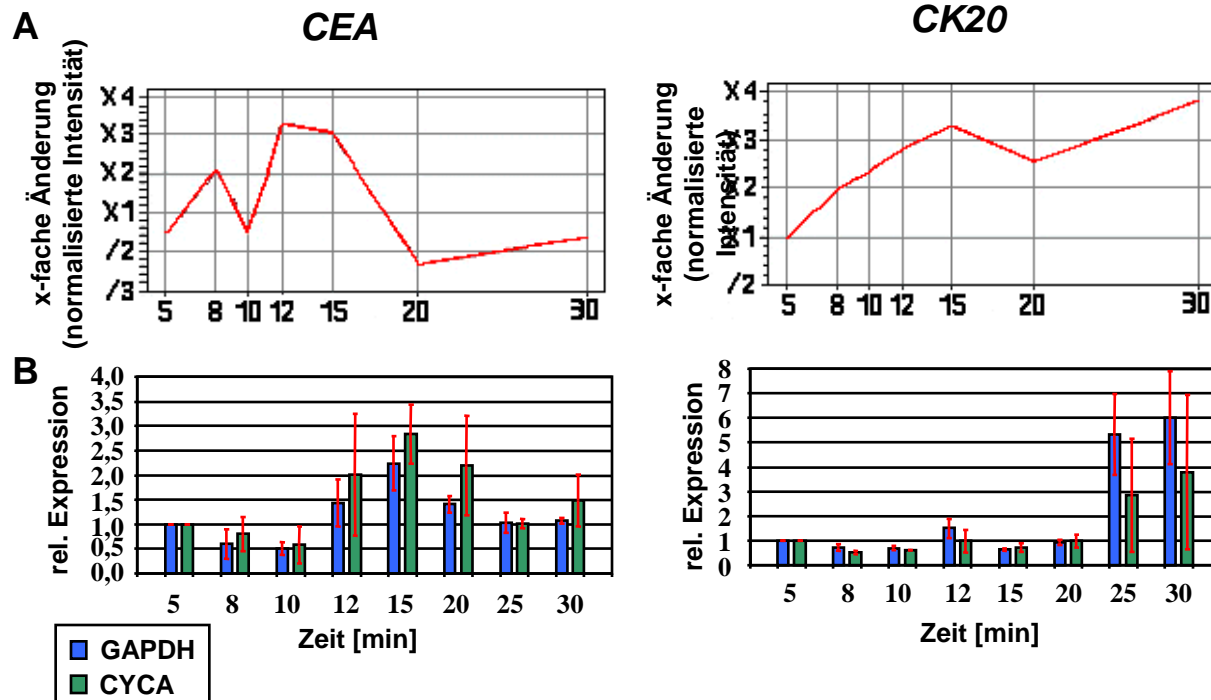
Time Between Ligation Of Main Artery And Tumor Resection (Intrasurgical Ischemia) Affects Gene Expression In Colon Cancer

Intrasurgical Ischemia



Postsurgical Ischemia and Gene Expression

Tumor marker *CEA* (colorectal cancer biomarker) and cytokeratin *CK20*

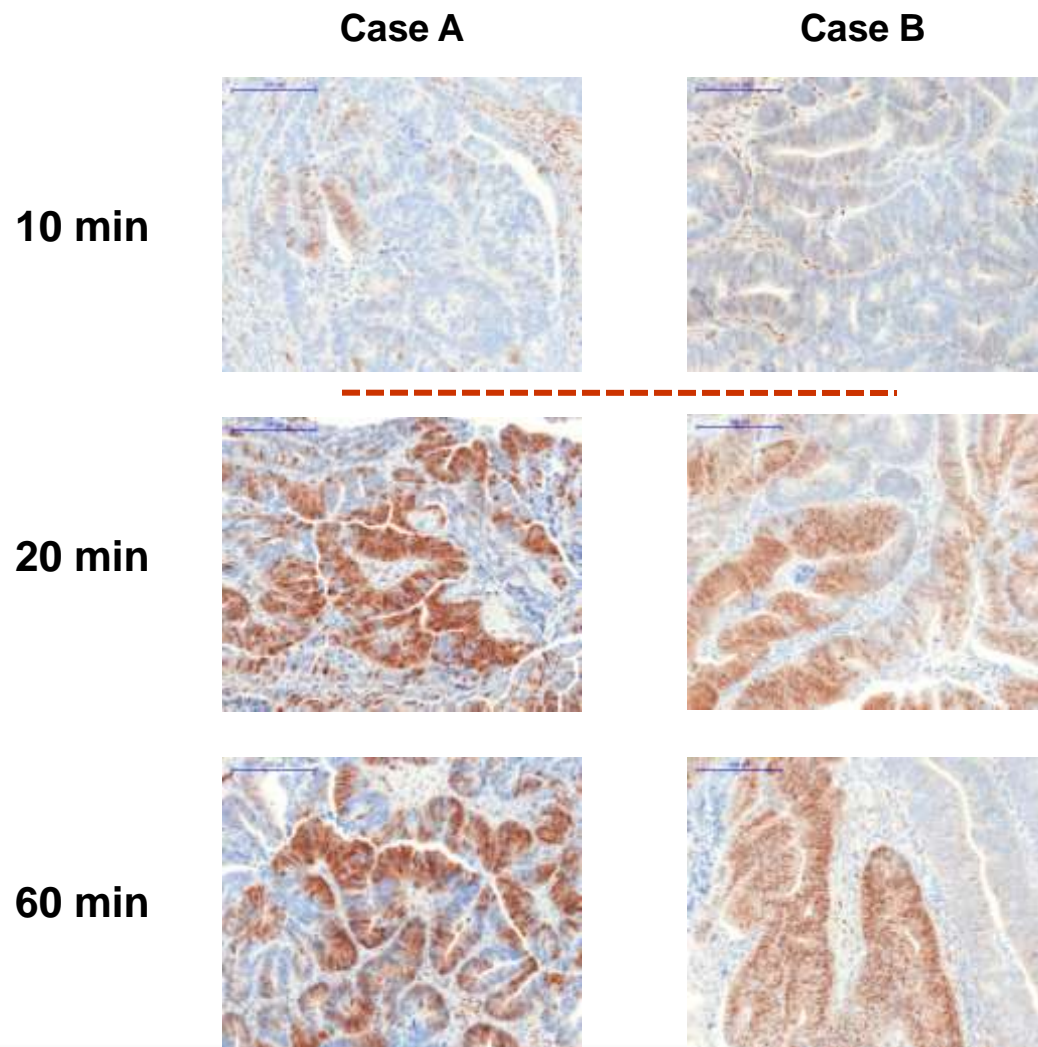


Tissue ischemia and gene expression profiling
(Comparison Affymetrix data and real-time RT-PCR)



Phosphoprotein Expression and Postsurgical Ischemia: pMAPK Immunostaining (Ventana)

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↑ Change of pMAPK expression
after 10-20 min cold ischemia
↓



Slide Compliments of Dr. Hartmut
Juhl, Indivumed GmbH, Hamburg



The Biospecimen Research Network (BRN): Improving the State of the Science

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- Sponsorship for new research: the BRN extramural research program
- Creation of IT tool to make existing and emerging biospecimen research data more accessible:
 - The Biospecimen Research Database (BRD): searchable web tool
 - Searchable by:
 - Specimen type
 - Variable type
 - Target molecule type
 - Analysis platform type
- Creation of data-driven SOPs for biospecimens used in research

[Learn more](#)



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Paper and Study Details

PubMed ID: 16288005

Lips Esther H, Dierrsen Jan WF, van Eijk Ronald, Oosting Jan, Eilers Paul HC, Tollenaar Rob AEM, de Graaf Eelco J, van't Slot Ruben, Wijmenga Cisca, Morreau Hans, van Wenzel Tom

Reliable high-throughput genotyping and loss-of-heterozygosity detection in formalin-fixed,paraffin-embedded (FFPE) tumors using single nucleotide polymorphism arrays.

Cancer Res, 2005, Vol. 22, Page 10188

Review Paper? No

Purpose of Paper: To determine if genomic DNA isolated from formalin fixed paraffin embedded (FFPE) tissue is applicable for genotype and loss of heterozygosity (LOH) analysis via single nucleotide polymorphism (SNP) arrays.

Conclusion of Paper: Results of SNP and LOH analyses were nearly identical among FFPE and frozen specimens. The authors conclude that genome wide genotyping using FFPE tissue is reliable, producing results that are reproducible with frozen specimens.

Studies

Detail	<p>Specimen: Tissue / Colorectal / Formalin / Normal</p> <p>Platform: DNA - SNP assay /</p> <p>Findings : The occurrence of SNPs in FFPE and frozen matched controls were nearly identical (99.9%). Of the 8 LOH regions examined only 2 were not identical among FFPE and frozen specimens (located on chromosomes 3 and 8). Genotyping results were identical among the two SNP arrays (BeadArray and GeneChip).</p>
Detail	<p>Specimen: Tissue / Colorectal / Formalin / Normal</p> <p>Platform: DNA - DNA Sequencing /</p> <p>Findings : DNA sequence analysis confirmed SNP results.</p>

Studies[Detail](#)

Specimen: Tissue / Prostate / OCT / Neoplastic - Carcinoma

Platform: RNA - cDNA Microarray /

Findings : Identified 61 statistically significant genes that were over expressed after 1 hr at room temperature -- 41 of which were previously identified named genes. Several of these genes are known to be early response gene, genes implicated in hypoxia, or transcription factors, including jun B proto-oncogene (JUNB), jun D proto-oncogene (JUND), and activating transcription factor 3 (ATF3). In contrast, expression of several genes implicated in prostate cancer development, e.g., hepsin, AMACR, fatty acid synthase, PTEN, and PIM-1, remained relatively constant. Early growth response 1 (EGR1), which has previously been shown to function as a master switch to activate several cellular responses to ischemic stress and has been previously associated with prostate cancer, had increased expression with increased incubation time at room temperature before processing. Therefore, processing time (i.e., time at room temperature before processing) may introduce artifacts into the gene expression profile for prostate tissue specimens.

[Detail](#)

Specimen: Tissue / Prostate / OCT / Neoplastic - Carcinoma

Platform: Protein - Westerns /

Findings : EGR1 protein expression increased with time that specimens sat at room temperature before being processed. Therefore, increased protein expression of EGR1 in prostate tissue specimens may be an artifact of processing time.



OBBR's Strategic Plan

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Providing Resources for the Research Community: The Cancer Human Biobank (caHUB)

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The vision:

- unique, centralized, non-profit public resource
- source of adequate and continuous supplies of human biospecimens and associated data of *measurable, high quality* acquired within an ethical framework
- source of high-quality biobanking services for the community



caHUB The Cancer
Human Biobank

caHUB Key Concepts

- Scientifically designed collection strategies (including rare diseases)
- Multiple aliquots of every specimen
- Standardized, annotated collection, processing of all specimens
- Centralized QC and pathology analysis of every specimen
- Rich, standardized data profile for each sample
- Centralized source of normal human specimens
- Provision of tools, resources, training for U.S. biospecimen resources



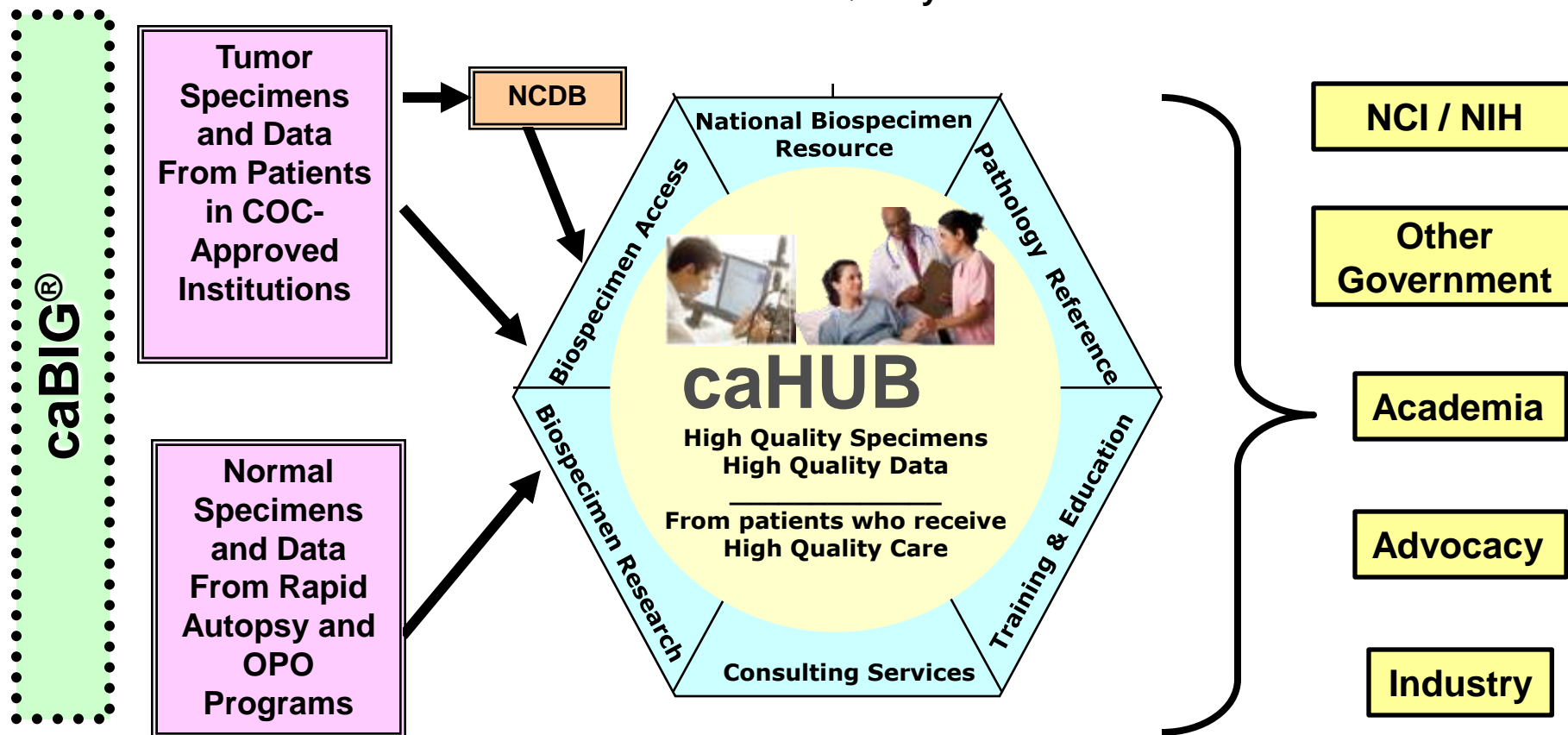


Defining the Need for caHUB

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- The need for caHUB has been clearly enunciated from all sources:
 - Survey of 5000 trans-NCI investigators (750 respondents)
 - Direct input to OBBR from potential users: CTEP, NCI Patient Characterization Center (PCC), numerous biomarkers programs
 - Mining of request data from the NCI Tissue Locator: last 7 years
 - Market research using focus group sessions with academia and industry decision-makers (OMB-approved; Strat@com-executed)
 - Focus group upcoming for regulators
 - Interviews with commercial tissue providers and industry users (economics considerations study by Booz Allen Hamilton)
 - caHUB Users Workshop

Centralized Resource: Cost and Quality Control Efficiencies





caHUB Collection Design: Informed by User Need

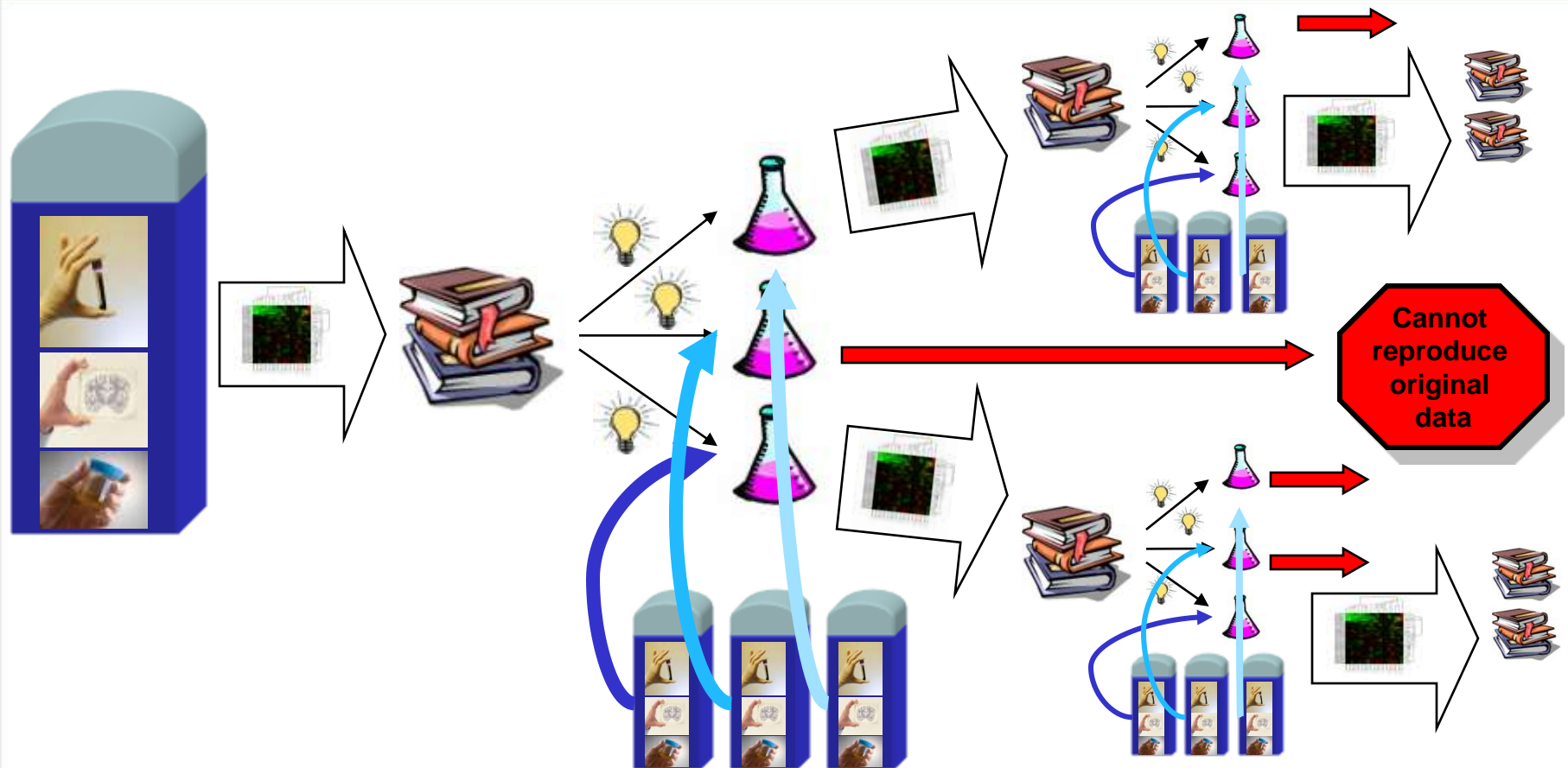
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In high demand and short supply:

- Benchmark samples
 - Collected through standardized methods with strict quality control and metrics
 - Data associated with process variables
- Cases with multiple aliquots
 - Confirmation of prior studies
 - Opportunity to extend prior studies based on new technologies / analyses
- Statistically valid numbers of biospecimen sets
- Fully defined “patient case sets”
 - Tumor
 - Adjacent normal tissue
 - Tumor periphery (invasive border)
 - Pre- and post operative blood samples
 - Urine
 - **Rich clinical data and outcome information for patients**
- Non-surgical samples: normal tissues; metastases; pre-malignancy

Biospecimen Variation Thwarts Innovation in Medical Science

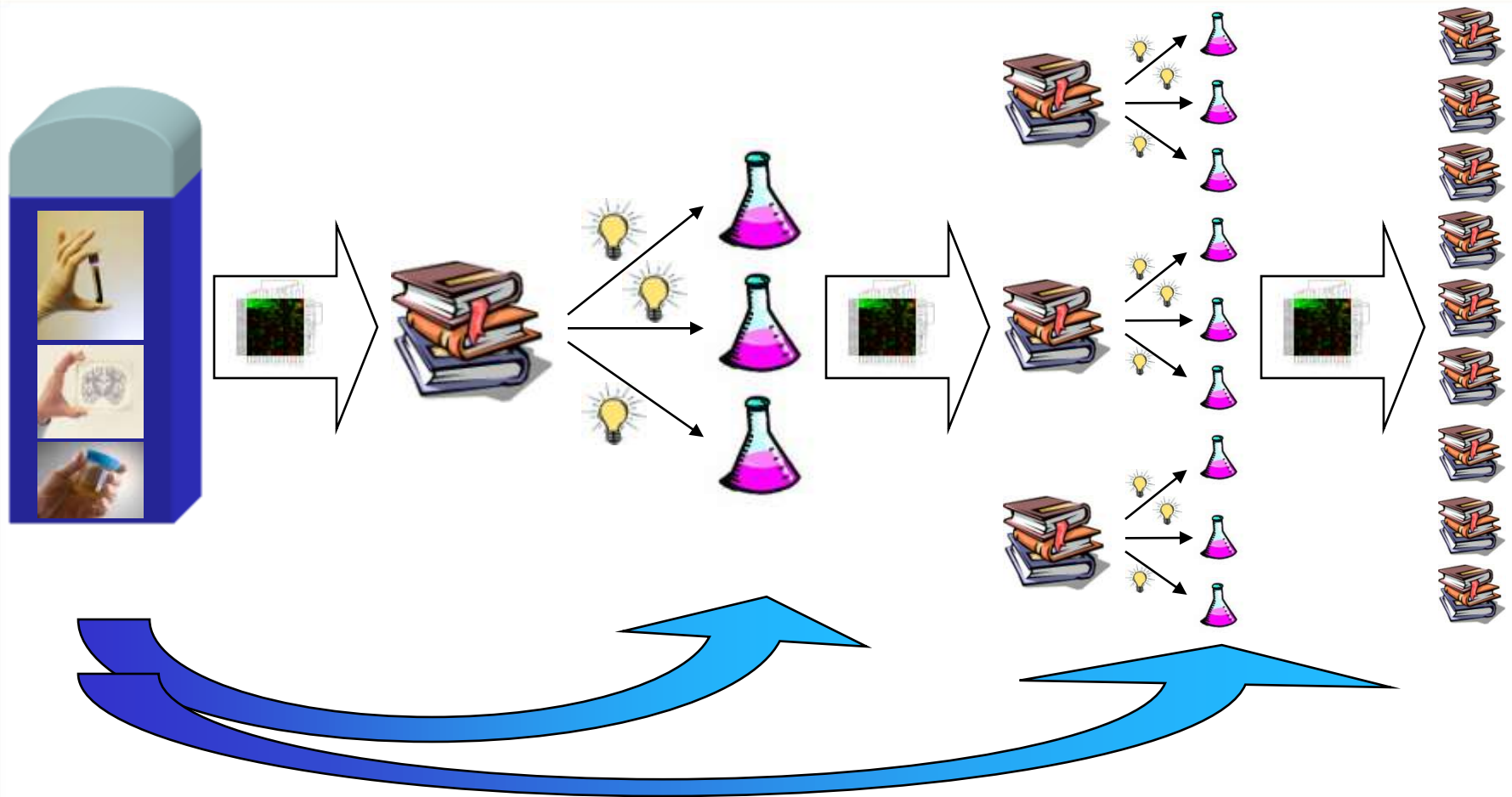
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Scientific Progress?

Biospecimen Standardization Advances Innovation in Medical Science: Building on Past Discoveries

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Scientific Progress



Informatics Goal for caHUB

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- Establish a comprehensive informatics tools and infrastructure that enables the tracking and sharing of specimens and associated data of many types with the research community.
- Deliverables include:
 - An integrated system that manages the collection and analysis of data related to biobanking and business operations, clinical data, specimen analysis data, and quality management
 - Fully operational informatics portal that provides a central access point that links to all caHUB related databases with the appropriate permissions established for each user group
 - An interface between caHUB and the National Cancer Database (NCDB) that leverages and expands the current NCDB functionality
 - Audits of data quality and information security

Data Supporting the Business Functions of caHUB



Infrastructure and Administration

- Bioinformatics Core/IT
- Building and Facilities
- Management and Personnel

5

1

Biospecimen Collection and Shipping

- Tissue Collection
- Preliminary Pathology and Histology Review
- Quality Validation
- Specimen Recording
- Consent Documentation
- Barcode Labeling and Scanning
- Data Collection
- Packaging and Shipping

2

Biospecimen Processing

- Detailed Pathology, Imaging, and Molecular Analysis
- Bioinformatics System Data Entry
- Link Assay, Test Results and Annotation to Specimens
- Barcode Labeling and Scanning

3

Biospecimen Storage Management

- Liquid Nitrogen, -80, and room Temperature Storage
- Inventory Control
- Barcode Scanning
- Freezer Room Monitoring and Physical Security
- Climate Control/Backup/Alarm Systems
- Periodic Auditing of Inventory

4

Biospecimen Retrieval and Distribution

- Specimen Retrieval Equipment
- Barcode Scanning
- Packing and Shipping
- Inventory Reconciliation
- Validation of Customer Receipt
- Customer Sales and Invoicing



The caHUB as a Data Resource for Users

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- **Data available through the system:**
 - Specimen type, amount, diagnosis, pathological characteristics, macro- and microscopic appearance
 - Collection, processing, storage, distribution
 - Quality control metrics
 - Clinical information about the patient/donor at multiple time-points
 - Molecular analysis results from different platforms
- **The comprehensive data base may, with maturation over time, become more useful to the scientific community than the specimens themselves (in silico research)**

caHUB, A Transformative Initiative



Annual Special Issue

TIME

10 IDEAS CHANGING THE WORLD RIGHT NOW

The global economy is being remade before our eyes. Here's what's on the horizon

- WHY YOUR JOB IS YOUR MOST VALUABLE ASSET
- REPURPOSING THE SUBURBS
- SURVIVAL-STORE SHOPPING
- BIOBANKS: SAVING YOUR PARTS
- NEED LAND? RENT A COUNTRY
- THE NEW CALVINISM
- ECOLOGICAL INTELLIGENCE
- AMORTALITY: FOREVER YOUNG
- AFRICA: OPEN FOR BUSINESS
- REINVENTING THE HIGHWAY

8. Biobanks By ALICE PARK

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Inside Huntsman Cancer Institute's vaults: Pancreatic tumors on ice. Lance W. Clayton for TIME

Folks at the National Cancer Institute (NCI) are heading up an effort to establish the U.S.'s first national biobank — a safe house for tissue samples, tumor cells, DNA and, yes, even blood — that would be used for research into new treatments for diseases.... By fall, the group hopes to have mapped out a plan for a national biobank; the recent stimulus showered on the government by the Obama Administration might even accelerate that timetable.

Time Magazine March 23, 2009

Time Magazine November 25, 2009



OBRR

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Biospecimen Data Is Critical to Realizing Personalized Medicine

Carolyn C. Compton, M.D., Ph.D.

Director, Office of Biorepositories and Biospecimen Research

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NATIONAL
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COVER

Animating a Blockbuster: How
Pixar Built Toy Story 3

FEATURE

Geek Gardening: A Wired
Guide to Domestic
Terraforming

LATEST

Most Dangerous Object in the
Office: Fire Footbag

MAGAZINE

FEATURES 13.08

Libraries of Flesh: The Sorry State of Human Tissue Storage

By Steve Silberman  May 24, 2010 | 12:00 pm | Wired June 2010



Photo: Andrew Tingle

Of all the forms of woe that take root in the human genome, the cancer called *Glioblastoma multiforme* is one of the most merciless. It can infiltrate the brain's white matter for months before causing any symptoms. By the time memory loss and seizures reveal the presence of an invader, there's often little to do but minimize the patient's suffering. Most who are diagnosed with the disease—people like the late senator Edward Kennedy—are dead within two years.

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The Challenge for the NCI

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Consensus of the Broad Scientific Community:

The lack of high-quality, clinically annotated human specimens has become the limiting factor for translational cancer research.





NCI's Biospecimen Activities: A Short History

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2010

- NCI Best Practices for Biospecimen Resources updated and expanded
- caHUB RFPs released

2009

- Cancer Human Biobank (based on NBN) planning takes place
- Widespread adoption of NCI BPs throughout NCI extramural biorepositories
- Biospecimen Research Network launched; First projects funded

2008

- FGGs revised and renamed NCI Best Practices for Biospecimen Resources
- Biospecimen Research Network concept approved; First Symposium held

2007

- First-Generation Guidelines for NCI-Supported Biorepositories (FGGs) developed by OBBR and BCC and published in Federal Register

2006

- Office of Biorepositories and Biospecimen Research established
- International Summit on Harmonization of biorepositories conducted
- caBIG™ software tools for biorepositories developed

2005

2004

- Analysis of NCI-supported biospecimen resources conducted
- Trans-NCI Biorepository Coordinating Committee (BCC) formed

2003

- Case Studies of Existing Human Tissue Repositories published
- National Biospecimen Network (NBN) Blueprint published

2002

- Biospecimen resources identified as critical resources for cancer research



NCI Best Practices Revision Process 2009

OBBR Office of Biorepositories
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- The 2007 *NCI Best Practices* were revised and updated by the BCC
- Perspectives from multiple OBBR-sponsored workshops included
- Comments from relevant NIH and HHS offices were incorporated
- Public comment on the *NCI Best Practices* to be sought through a Federal Register notice beginning this month
- The updated BPs will continue to use an online format and will focus on providing additional appendices/resources for detailed information

2009 Web-based Format: NCI Best Practices

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The screenshot shows the NCI Best Practices website as it appeared in 2009, viewed through a Microsoft Internet Explorer browser. The browser's address bar displays the URL <http://biospecimens.cancer.gov/bestpractices/>. The website's header features the National Cancer Institute (NCI) logo and the text "National Cancer Institute" and "U.S. National Institutes of Health | www.cancer.gov". Below this, the "OBBR" logo is prominently displayed, followed by the text "NCI Best Practices for Biospecimen Resources" and "Office of Biorepositories and Biospecimen Research". A navigation bar includes links for "Home", "Sign Up For Updates", and a search function labeled "Search NCI Best Practices". Below the navigation bar, there are three main action buttons: "Sign Up For Best Practices Updates", "Please Provide Us Your Feedback", and "Take Our Poll And See What Others Are Saying". The main content area is divided into two columns. The left column contains a vertical menu with links to various sections: "Introduction", "Scope, Applicability, Implementation", "Technical and Operational Best Practices", "Ethical, Legal, and Policy Best Practices", "References", "Web Resources", "Glossary of Terms", "Acronym List", "Appendix 1: NCI Infrastructure to Support Informatics Best Practices", "Appendix 2: Material Transfer Agreement (PDF)", and "NCI Best Practices for Biospecimen Resources (PDF)". The right column contains the main text of the page. It begins with an introductory paragraph stating that the NCI Best Practices were developed to address the lack of standardized, high-quality biospecimens. This is followed by a section titled "Scope, Applicability, Implementation" which includes a list of key principles: "define state-of-the-science biospecimen resource practices", "promote biospecimen and data quality", and "support adherence to ethical and legal requirements". Below this, another section titled "Technical and Operational Best Practices" explains that these principles are intended to guide procedures developed by biospecimen resources. The website's footer shows the Windows taskbar with several open applications, including "Inbox - Microsoft Outlook", "Microsoft PowerPoint", and "Hospital Consent princ...", along with the system clock showing "11:45 AM".

Home Page - OBBR Best Practices - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address <http://biospecimens.cancer.gov/bestpractices/> Go Links

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

OBBR NCI Best Practices for Biospecimen Resources Office of Biorepositories and Biospecimen Research

Visit the OBBR website

Home | Sign Up For Updates

Search NCI Best Practices

Sign Up For Best Practices Updates Please Provide Us Your Feedback Take Our Poll And See What Others Are Saying

Introduction

Scope, Applicability, Implementation

Technical and Operational Best Practices

Ethical, Legal, and Policy Best Practices

References

Web Resources

Glossary of Terms

Acronym List

Appendix 1: NCI Infrastructure to Support Informatics Best Practices

Appendix 2: Material Transfer Agreement (PDF)

NCI Best Practices for Biospecimen Resources (PDF)

One of the most widely recognized and significant roadblocks to progress in cancer research is the lack of standardized, high-quality biospecimens. The National Cancer Institute (NCI) developed the NCI Best Practices for Biospecimen Resources (NCI Best Practices) based on extensive research and expert input into the state of NCI-funded biospecimen resources and the quality of biospecimens used in cancer research. The NCI Best Practices outline the operational, technical, ethical, legal and policy best practices for NCI-supported biospecimen resources.

Scope, Applicability, Implementation

The NCI Best Practices incorporate key principles that:

- define state-of-the-science biospecimen resource practices
- promote biospecimen and data quality
- support adherence to ethical and legal requirements

The NCI Best Practices define principles to guide procedures developed by biospecimen resources. They are intended to be adopted based on the mission and scientific needs of biospecimen resources. While adoption of the NCI Best Practices is voluntary, the NCI believes that these principles optimize biospecimens for cancer research. [Learn more](#)

Technical and Operational Best Practices

Although the specific mission of a biospecimen resource will define its collection and processing procedures, common principles apply to all biospecimen types. The best practices within this section are based on current, published information and will be revised periodically as new

<http://biospecimens.cancer.gov/bestpractices>



Features of New Interactive Format

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Additional capabilities include:

- Hyperlinks to outside resources and references
- Internal links between various sections within the *NCI Best Practices*
- Search functionality of *NCI Best Practices* content

Interactive features to encourage stakeholder input:

- Feedback form
- Polls
- Sign-up form for updates on the *NCI Best Practices*



Highlights of Revisions to NCI Best Practices

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- **Technical and Operational Practices**
 - New section “Biospecimen Resource Management and Operations”
 - Updated references & websites for further information throughout
 - Perspectives from OBBR workshop on Biobanking Economics
- **Ethical, Legal and Policy Issues**
 - Perspectives based on the findings of OBBR-NCI workshops:
 - Custodianship / Ownership
 - Pediatric Consent
 - Revised informed consent, withdrawal of consent and privacy recommendations to reflect current US federal guidance
 - New section on “Conflicts of Interest” to coincide with new NIH policy
- **New Appendices**
 - “Minimal Clinical Data Set”
 - Template biospecimen resource “Governance Plan”
 - Compilation of resources related to Ethical, Legal and Policy Issues



BRN Extramural Research Will Benefit the Entire NCI Community

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- Biospecimen molecular integrity:
 - Effects of blood specimen handling procedures on protein integrity
 - Credentialing plasma and serum biospecimen banks for proteomics
 - Intrinsic and extrinsic controls for FFPE tissue
 - Effects of biospecimen integrity on microarray-based pharmacogenomics tests of breast cancer
- Tissue acquisition process variables and molecular analysis results:
 - Define the procedural variations that cause the most significant variations in molecular composition and integrity
 - Time to fixation
 - Length of fixation
 - Different processing parameters
 - Use this data to inform the development of evidence-based Standard Operating Procedures (SOPs)



IMAT: Technology Solutions for Molecular Analysis with Broad Benefit

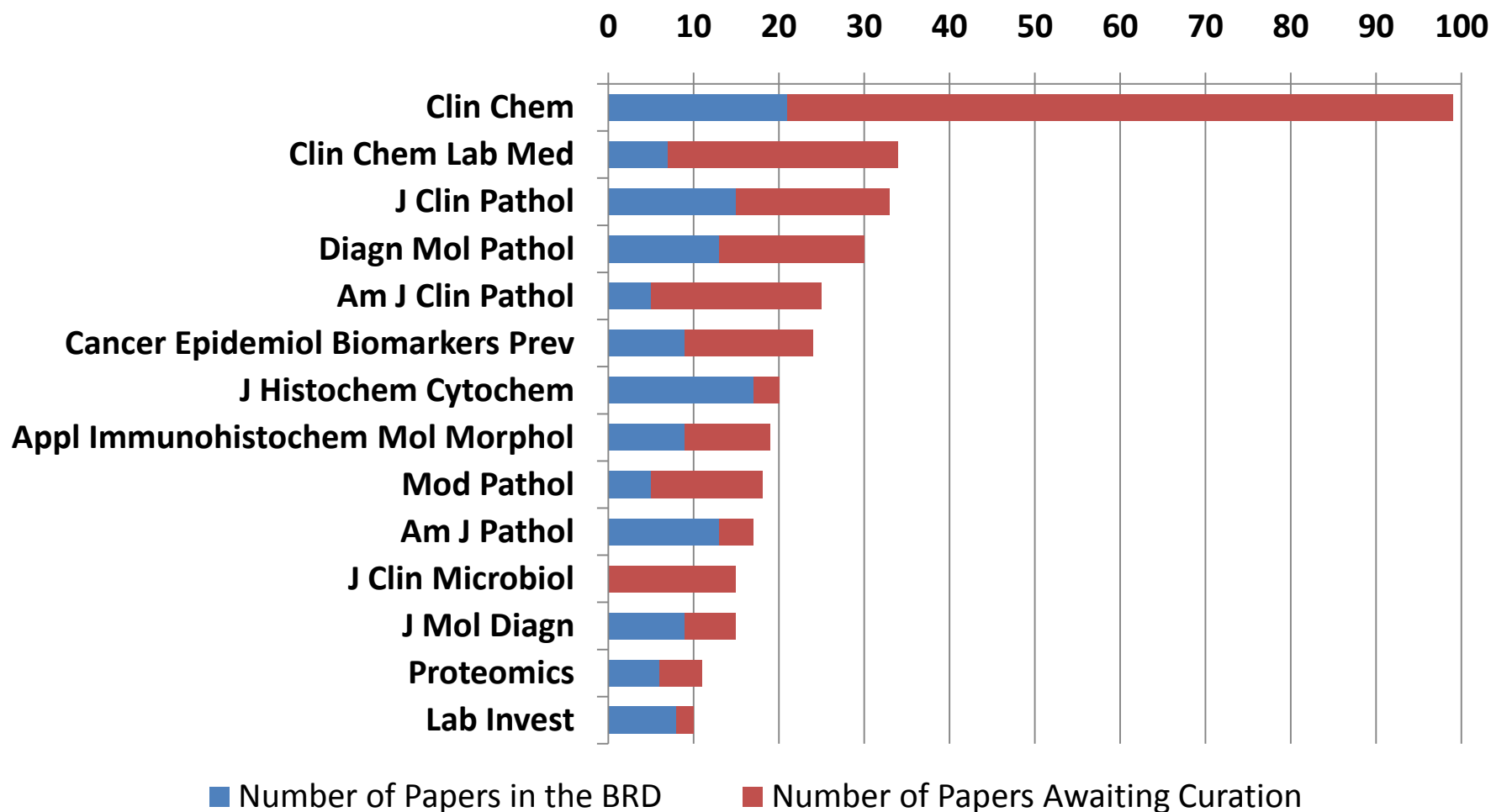
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and Biospecimen Research

- **Key features:**

- Coordinated through OBBR; managed through the divisions
 - Trans-NCI needs are addressed through centralized approach
- Innovation-focused, early stage technology development
 - High-risk, high-impact
- Cutting-edge ideas through commercialization
- Block-buster incubator:
 - RNeasy®
 - Affymetrix chips
 - Illumina beads
 - MudPit
 - Protein arrays (Micro-proteomic profiling of FFPE)
 - Quantum dots
 - Cold PCR
 - RainDance ®
- Commitment to diversity: CHCRD training/teaching collaboration

300 papers now curated

Journals with 10 or More Papers Identified for BRD Inclusion





The caHUB Business Model: A Commodities and Services Model

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COMMODITIES: Cost Recovery

Distribution of specimens and data

Increasing value of aliquots over time with increasing data richness:

Time-dependent maturity

SERVICES: Revenue Generation

Build on existing infrastructure and improve return on investment:

Not time-dependent

➤ Biobanking services to other initiatives

- Other NCI/NIH
- Rare diseases
- Advocacy

➤ Education and training

- Pathology and laboratory functions
- Operating room functions
- IT and data management
- Biostatistical and analytic methods

➤ Consulting services

- Biobanking methods and best practices

➤ Biobanking support service to industry

- Assay development
- Clinical trials

➤ Laboratory space and services

- Research incubator functions
- Longer term in-house research contracts



OBBR's Role within the NCI Community

OBBR Office of Biorepositories
and Biospecimen Research

- Provide state-of-the-science guidance and tools for the use of human biospecimens in NCI research of all types
- Sponsor scientific investigation and educational activities that continually improves the scientific strength of all human specimen-related practices
- Sponsor technology development for human specimen-related needs
- Serve as a consultative resource for all biobanking activities across the NCI and the NIH
- Partner with professional organizations that are stakeholders in medical research and personalized medicine; harmonize national/international efforts
 - AACR, FDA, NIST, CAP, ACS, SPIDIA
- Fill the gap of availability of highest quality human biospecimens for research through implementation of standards of care in personalized medicine

Why Is It Difficult to Acquire High-Quality Specimens and Data?

- Collection, procession, storage procedures differ
- Degree and type of data annotation varies
- Scope and type of patient consent differs
- Access policies are lacking or unknown to potential users
- Materials transfer agreement conditions differ
- Supporting IT structures differ in capacity and functionality

→ **WIDE VARIATION IN QUALITY OF SPECIMENS AND DATA**